

CRITICAL DIAGNOSES (CRITICAL VALUES) IN ANATOMIC PATHOLOGY

Association of Directors of Anatomic and Surgical Pathology

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ABSTRACT

Similar to critical values in clinical pathology, occasional diagnoses in surgical pathology and cytology may require urgent contact of the physician to facilitate rapid intervention or treatment. However, there are no established critical value (critical diagnosis) guidelines in anatomic pathology. As discussed herein, the Association of Directors of Anatomic and Surgical Pathology (ADASP) believes that establishing anatomic pathology critical diagnosis guidelines represents a practice improvement and patient safety initiative. ADASP also recognizes that a generic anatomic pathology critical diagnosis guideline such as this should only be used as a template, since the list needs to be customized at each individual hospital following consultation with relevant clinical services. Based on surveys of the membership of the ADASP, this document provides examples of possible critical diagnoses in anatomic pathology.

The concept of critical values (CV) was first introduced by Lundberg in 1972 as a pathophysiologic derangement at such variance with normal as to be life threatening if therapy is not instituted immediately.¹ The practice assessment committee and board of directors of the American Society of Clinical Pathology (ASCP) presented practice parameter guidelines that included a generic CV clinical pathology list derived from interlaboratory surveys.² They recommended that every lab customize their CV list to meet the needs of the organization and that an institutional committee approve and periodically review and revise this list. They also recommended that there should be a strict semantic interpretation of which test results qualify as a CV and a process of reporting by phone or alpha numeric page any CV lab test result.² The Clinical Laboratory Improvement Amendments of 1988 (CLIA 88), section 493.1109, states that “the laboratory must develop and follow written procedures for reporting life-threatening laboratory results or panic values.³ In addition, the laboratory must immediately alert the individual or entity requesting the test or the individual responsible for utilizing the test results when any test results indicate an imminent life-threatening condition”.⁴ The Joint Commission on Accreditation of Health Organizations of the American Hospital Association (JCAHO) standard LD 3.2.1 requires that “approved criteria are established for the immediate notification of the responsible practitioner when critical limits of specified test results are exceeded”. In addition, one of the JCAHO’s 2005 national patient safety goals is “improved effectiveness of communication among care givers”⁵ “The measure

assesses and, if appropriate, takes action to improve the timeliness of reporting, and the timeliness of receipt by a responsible licensed care giver, of critical test results and values”.⁵

In the College of American Pathologists (CAP) Laboratory Accreditation Program, the laboratory general check list asks “does the laboratory have procedures for immediate notification of a physician (or other clinical personnel responsible for patient care) when the results of certain tests are within established “alert” “critical ranges”?”⁶ The 2005 CAP check list now includes a requirement asking, “is there a policy regarding the timely communication, and documentation thereof, of significant or unexpected surgical pathology findings?”⁷ This check list also elaborates that “certain surgical pathology diagnoses may be considered particularly significant or unexpected. Such diagnoses may include: malignancy in an uncommon location or specimen type (e.g., hernia sac, intervertebral disk material, tonsil, etc.), absence of chorionic villi when clinically expected (potential ectopic pregnancy), change of a frozen section diagnosis after review of permanent sections, and/or mycobacterial, fungal or other significant infectious organisms identified on special stains. Diagnoses to be defined as “significant” or “unexpected,” if any, should be determined by the pathology department, in cooperation with local clinical medical staff. Consideration should be given to assuring, with reasonable effort, prompt communication of such results, by telephone, pager, or other system. There should be documentation of date and time of such special notification

(which may be included in the pathology report or in laboratory files)”. Not meeting this requirement is a phase I deficiency.

Following the introduction of the critical value concept and the above regulatory and accreditation requirements, the practice of notifying physicians of critical values has become the standard of practice in clinical pathology, with well established guidelines for which specific laboratory results require that the laboratory personnel immediately contact the clinician or nurse responsible for the patient.⁸⁻¹⁴

However, there are no well-defined guidelines and there is scant literature addressing the concept of critical diagnoses (critical values) in anatomic pathology^{15,16}. Yet, most practitioners would agree that there are certain diagnoses in anatomic pathology that could require immediate treatment or prompt evaluation of the patient, satisfying the Lundberg concept of critical values.¹ Currently, in the absence of such guidelines, common sense and the personal experience of the pathologist determine when an immediate contact of the physician is needed. It is apparent from the few previous studies that there is a range of opinion among pathologists and between pathologists and clinicians about the need for clinician notification, the degree of urgency, and the method of communication to be employed^{15,16}.

The Association of Directors of Anatomic and Surgical Pathology (ADASP) endorses the concept of critical diagnoses (critical values) in anatomic pathology, recognizing that critical diagnosis guidelines would be helpful to practicing pathologists and ultimately to our clinical colleagues and patients.

Table 1 lists examples of possible critical diagnoses cases in anatomic pathology based on surveys of the ADASP membership.^{17,18} ADASP has not sought to define the manner in which such critical diagnoses might be optimally communicated since there will inevitably be variable local (institutional) systems and requirements in this regard.

Since the Institute of Medicine's report on medical errors, a number of initiatives have been instituted to improve patient safety.¹⁹ ADASP believes that establishing anatomic pathology critical diagnosis guidelines represents a practice improvement. We also recognize that generic anatomic pathology critical diagnosis guidelines should only be used as a template, since the list needs to be customized at each individual hospital based on specific requests from clinicians and institutional factors such as the scope of services provided, case mix, acuity level and protocols. Similar to the establishment of critical diagnoses in clinical pathology, consultation with relevant clinical services in the development of anatomic pathology critical diagnoses is important. In addition, similar to the approach in clinical pathology, it is important to avoid overuse and eliminate non-critical diagnosis-type cases.

In conclusion, ADASP supports the concept of critical diagnoses in anatomic pathology since surgical pathology and cytologic examination can occasionally identify abnormalities that can be potentially life threatening and require rapid corrective action for improvement of patient outcome. As such, establishing

critical diagnoses guidelines in anatomic pathology is an important patient safety initiative.

**TABLE 1: EXAMPLES OF CRITICAL DIAGNOSES IN ANATOMIC
PATHOLOGY**

CASES THAT HAVE IMMEDIATE CLINICAL CONSEQUENCES

- crescents in greater than 50% of glomeruli in a kidney biopsy
- leukocytoclastic vasculitis
- uterine contents without villi or trophoblast
- fat in an endometrial curettage
- mesothelial cells in a heart biopsy
- fat in colonic endoscopic polypectomies
- transplant rejection
- malignancy in superior vena cava syndrome
- neoplasms causing paralysis

UNEXPECTED OR DISCREPANT FINDINGS

- significant disagreement between frozen section and final diagnosis
- significant disagreement between immediate interpretation and final FNA diagnosis
- unexpected malignancy

- significant disagreement and/or change between primary pathologist and outside pathologist consultation (at either the original or consulting institution)

INFECTIONS

- bacteria or fungi in CSF cytology in immunocompromised or immunocompetent patients
- pneumocystis, fungi or viral cytopathic changes in bronchoalveolar lavage (BAL), bronchial washing or brushing cytology specimens in immunocompromised or immunocompetent patients
- acid-fast bacilli in immunocompromised or immunocompetent patients
- fungi in FNA of immunocompromised patients
- bacteria in heart valve or bone marrow
- herpes in Pap smears of near term pregnant patients
- any invasive organism in surgical pathology specimens of immunocompromised patients

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